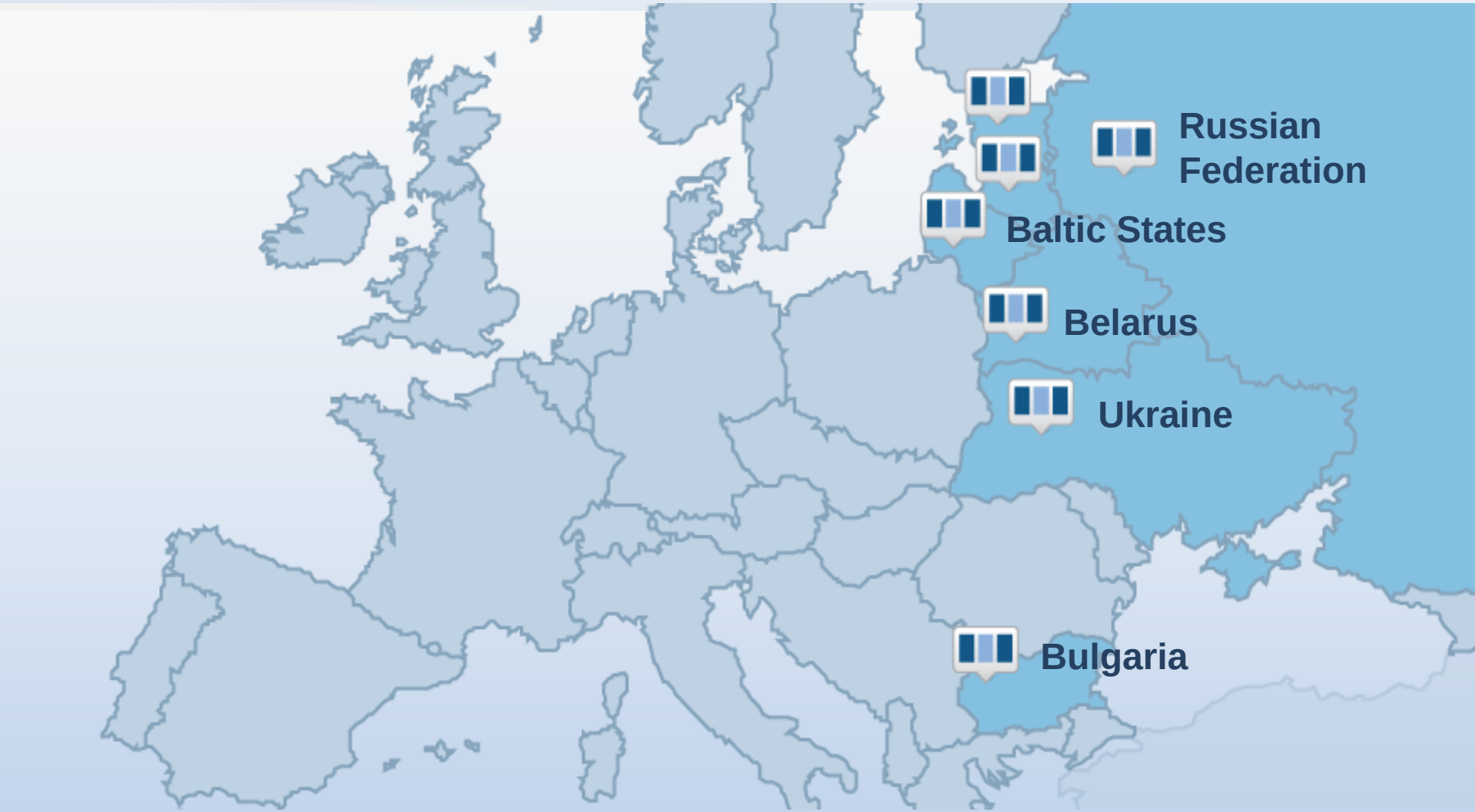
Our Advantage is our Commitment to Excellence

OCT GROUP

Full-service clinical trials in Central and Eastern Europe

OCT presence in CEE



OCT
clinical trials in CEE

Qualified clinical Investigators with experience
in ICH-GCP compliant industry-driven study

www.oct-clinicaltrials.com

OCT Offices

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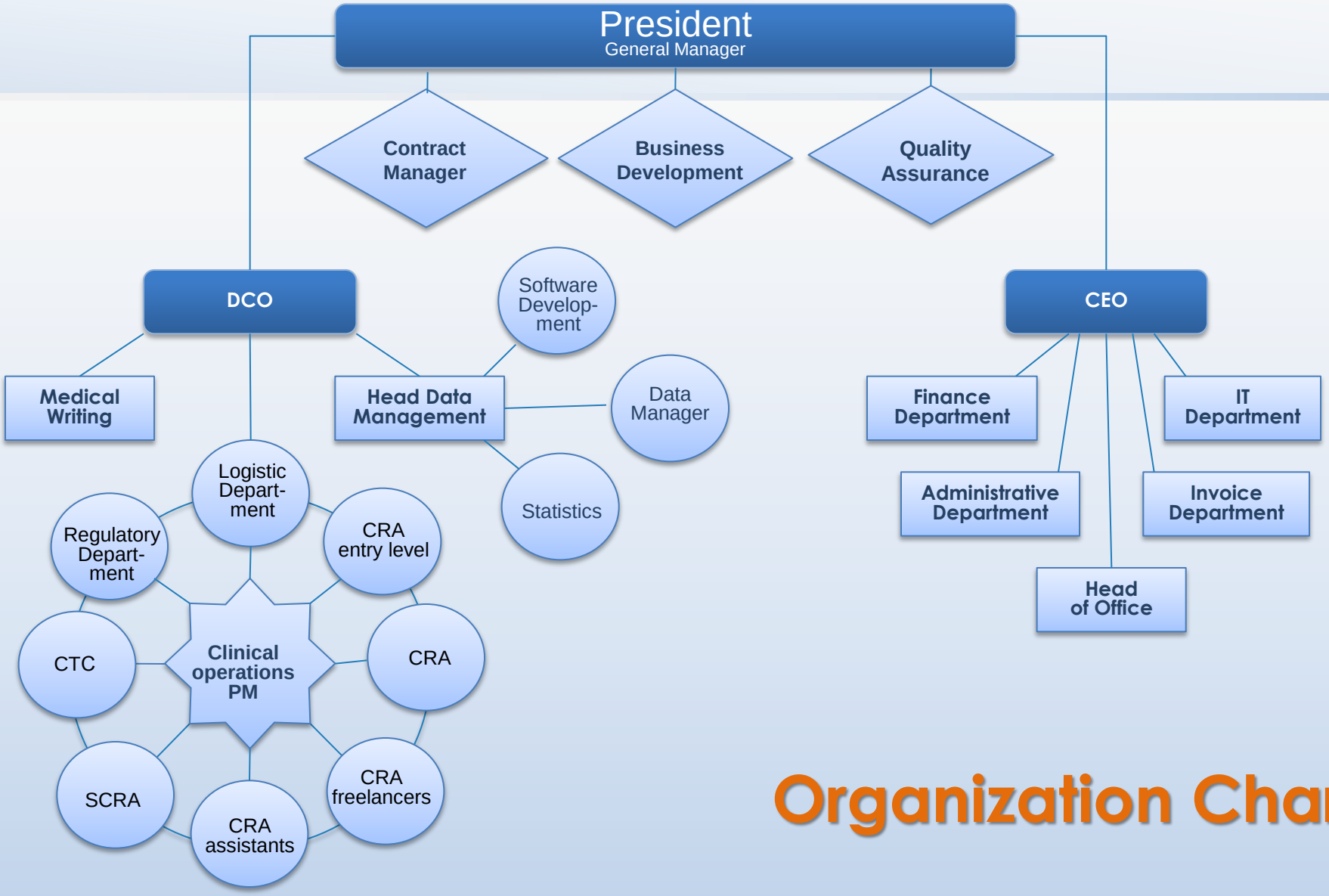

Organization Chart

OCT infrastructure in Russia

OCT
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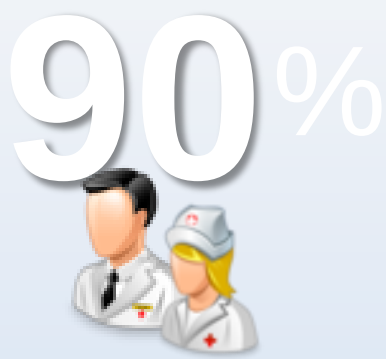
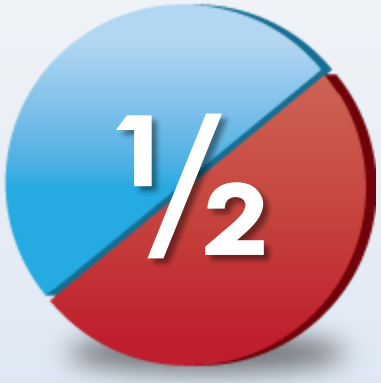
Clinical Staff

OCT Staff more than 85 people in total



90 % of CRAs and PMs are medical doctors



1/2 of the staff are in clinical department

Clinical Experience

Therapeutic Area	Indication	Phase
	2006	
Oncology	Immunotherapy in Renal Cell Carcinoma	**Phase III**
Oncology	T-cell Leukemia	**Phase II b**
Nutrition/Pediatrics	Prevention of common infectious disease	**Phase III–IV**
Dermatology	Acne	**Phase II–III**
Cardiology	Acute Heart Failure	**Phase III**
	2007	
Oncology	Breast Cancer	**Phase II**
Gastroenterology	Crohns disease	**Phase II**
Oncology	Prostate Cancer	**Phase II–III**
Oncology	Breast cancer	**Phase II**
Cardiology	Acute Myocardial Infarction + LVH	**Phase IV**
Gastroenterology	Irritable Bowel Syndrome	**Phase III**
Oncology	Breast Cancer, neutropenia	**Phase III**
	2008	
Oncology	Bone metastases, pain	**Phase II**
Ophthalmology	Age-related macular degeneration	**Phase I**

Clinical Experience

Therapeutic Area	Indication	Phase
	2008	
Oncology	Prostate cancer	**Phase III**
Neurology	Brain vessel aneurysm rupture	**Phase III**
Endocrinology	Diabetes Mellitus	**Phase II**
Oncology	Ovarian Cancer	**Phase III**
Autoimmune disorders	Rheumatoid arthritis	**Phase II**
Oncology	Breast Cancer	**Phase III**
Oncology	Solid tumors	**Phase I**
	2009	
Gastroenterology	H. Pylori	**Phase II**
Endocrinology	Hypothyriosis	**Phase IV, register**
Gastroenterology	Liver diseases	**Post-marketing**
Endocrinology	Diabetes Mellitus	**Phase II**
Urology	Erectile Dysfunction	**Phase III**
Oncology	Breast cancer	**Phase II**
Cardiology	Hypertension+LVH	**Phase IV**
Hepatology	Hepatic cirrhosis	**Phase III**

Clinical Experience

Therapeutic Area	Indication	Phase
	2010	
Oncology	Advanced cancer/solid tumor	**Phase I-IIa**
Surgery	Pain	**Phase II**
Pediatrics Gastroenterology, Neonatology	Flatulence, intestinal colics	**IV, register**
Oncology	Metastatic breast cancer	**Phase II**
Cardiology	Hypertension	**Phase II**
Neurosurgery	Aneurism rupture	**Phase III**
CNS	Bioequivalence	**BE/PK**
Endocrinology	Autoimmune thyroiditis	**Phase IV**
Oncology	Cancer	**Pre-clinical**
Neurology	Multiple Sclerosis	**Phase IV, register**
Oncology	Colorectal cancer	**Phase III**
Oncology	Endometrial cancer	**Pre-clinical**
Oncology	Solid tumors	**Phase II**

Clinical Experience

Therapeutic Area	Indication	Phase
	2010	
Gastroenterology	Liver disorder	**Phase IV, register**
Traumatology, orthopedics	Major joints surgery	**Phase III**
Pulmonology, Pediatrics	Bronchitis, pneumonia, asthma	**Phase IV, register**
Respiratory	Sore throat associated with URTI	**Phase II**
Oncology	Ovarian cancer	**Phase III**
Oncology	Metastatic breast cancer	**Phase II**
Otorinolaringology	Rhinitis	**Phase IV, register**
Oncology	Endometrial cancer	**Phase II-III**
Surgery	Colorectal anastomosis	**Pilot (device)**
Pediatrics	Acute bronchitis	**Phase IV**
Systemic diseases	Mastocytosis	**Phase II**
Pediatric/gastroenterology	Intestinal colics	**Phase II**
Infectious diseases	HDV	**Phase I**
Oncology	Colorectal cancer	**Phase II**

Clinical Experience

Therapeutic Area	Indication	Phase
	2011	
Poisoning	Sedation of benzodiazines	**Phase III**
CNS	Healthy volunteers	**BE**
Oncology	Multiple myeloma	**Phase III**
CNS	Multiple sclerosis	**Phase I**
Oncology	Breast Cancer	**Phase I-II**
Oncology	Cancer	**Pre-clinical**
Cardiology	Hypertension	**Phase III**
Psychiatry	Alcohol addiction	**Phase I in healthy volunteers**
Surgery	Ischemic foot ulcers	**Phase III**
Oncology	Solid tumors	**Phase I-II**
CNS	Hemispheric ischemic stroke	**Phase IV**
Otolaryngology	Stable angina	**Phase IV**
Oncology	Cancer	**Pre-clinical**

Clinical Experience

Therapeutic Area	Indication	Phase
	2011	
Oncology	Locally Advanced Pancreatic Adenocarcinoma	**Phase II**
Internal diseases	Chronic fatigue	**Phase I in healthy volunteers**
Oncology	Colorectal cancer	**Phase III**
Oncology	Bladder cancer	**Phase II**
Respiratory diseases	Asthma, COPD	**Phase III**
Oncology	Head and neck cancer	**Phase III**
Therapy	Arthrosis, Polyarthritis	**BE**
Cardiology	Isolated systolic hypertension	**Phase III**
Pediatrics	Colitis	**Phase II**
Oncology	Advanced solid tumors	**Phase I b**
Therapy	Myalgia, arthritis	**Phase III**
Pulmonology	Bronchitis, Pneumonia	**BE**
Rheumatology	Gout	**Phase III**
General medicine	Wound healing	**Phase II; device**

Clinical Experience

Therapeutic Area	Indication	Phase
	2011	
Gastroenterology	Spasms, colonoscopy	**Phase III**
Therapy	Central catheter's maintenance	**Phase II**
Surgery	Parenteral nutrition	**Phase III**
Rheumatology	Rheumatoid arthritis, psoriasis	**Phase IIb-III**
Poisoning	Healthy volunteers	**Phase I**
Oncology	Neutropenia in breast cancer	**Phase I-II**
Neurology	Pregnancy registry, multiple sclerosis	**Post-marketing**
Pain	Healthy volunteers	**Phase I**
Urology	Benign prostatic hyperplasia	**BE**
Oncology	Solid tumors	**Phase I**
Virology	Healthy volunteers	**Phase I**
Gynaecology	Mastalgia	**Phase III (registration)**

Clinical Experience

Therapeutic Area	Indication	Phase
	2012	
Neurology	Multiple sclerosis	**Bioequivalence**
Oncology	Prostate Cancer	**Bioequivalence**
Oncology	AML	**IIa**
Infectious disease	HBV	**IIa**
Pediatrics	Pain and inflammation	**BE**
Oncology	Neutropenia	**IIb**
Oncology	Solid tumors	**Pre-clinical**
Pain	Pain and inflammation	**BE**
Consultancy	Development of a regulatory strategy	**Consultancy**
Consultancy	Interpretation of guidelines	**Consultancy**
Oncology	Advanced melanoma	**I**
Cardiology	Coronary artery disease	**IV**
Respiratory	Sore throat	**III**

Clinical Experience

Therapeutic Area	Indication	Phase
	2012	
Oncology	Breast cancer	**II**
Cardiology	Non-valvular atrial fibrillation	**IV**
GCP Training	GCP Training	**GCP Training**
Oncology	Head and neck cancer	**Medical writing**
Otolaryngology	Sore throat	**III**
Neurology	Vascular dementia	**Medical writing, consultancy**
Therapy	Pain	**III**
Medical Writing Training	Medical Writing Training	**Medical Writing Training**
Cardiology	Atherosclerosis	**I-II**
NSAID / Ophtalmology	Postoperative ocular inflammation / pain	**III**
NASID / Rheumatology	Arthritis / pain	**Bioequivalence**

Services provided by OCT

- Consulting
- Medical writing
- Feasibility assessment
- Project management
- Regulatory support
- Clinical monitoring
- CRA training
- Logistics support
- Quality assurance, Audits
- Purchase of concomitant medication
- Data management
- Statistics
- Safety Management


Clinical trials
HOW WE DO IT
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Consulting and Medical Writing

- Consulting and Medical Writing
- Study design in country-specific environment
- Sample size calculation
- Development of study essential documents
- Study protocol
- Informed Consent Form
- Investigators' Brochure
- IMPD review
- Strategic clinical development planning

Project Management

- Primary client contact and every-day communication
- Project planning
- Ensuring strict adherence to project timelines, budget, and quality performance in accordance with CFR 21/ICH GCP and local regulations
- Team trainings
- Principal Investigator selection
- Investigators' Meeting preparation

Assuring quality of monitoring

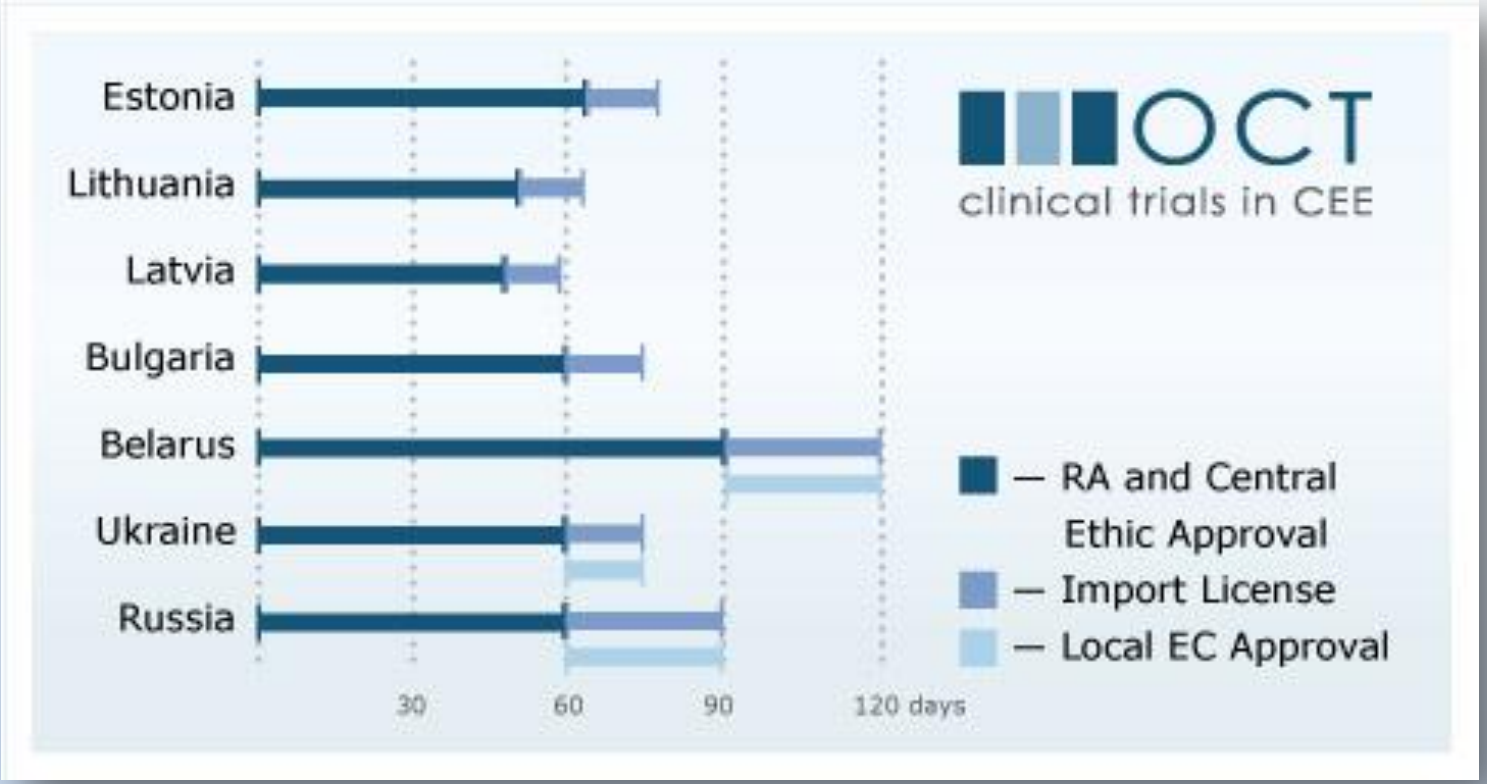
- Medical Doctors on staff
- Monitors have at least 2 years of experience
- Accumulated experience in all therapeutic areas
- Team trainings
- Second person review of monitoring reports
- Internal audits
- Site selection based on experience
- Co-monitoring
- Project review meetings

Regulatory support

- Translation (when applicable)of essential study documents required for submission
- Adjustment of informed consent forms to country-specific requirements, cultural adaptation
- Collection of documents required for submission from investigators
- Arrangement of local insurance
- IMPD preparation if required
- Preparation and QC of the submission application
- Submission of the clinical trial application to regulatory authorities and ethics bodies
- Communication with regulatory authorities and ethics bodies if required
- Export / import license

Regulatory approval timelines

Average time from application submission
to final study approval (days)



Logistics support

- Import of drugs, laboratory kits, other supplies
- Export of biologic samples
- Customs clearance
- Shipments tracking
- Clinical trial materials distribution to sites
- Collection of biologic samples from sites
- Biosample export to central laboratories

DM and Biostatistics

- EDC System development (CDISC CDASH compliance)
- Double data entry (for paper CRF)
- Clinical trial database creation and maintaining
- Data cleaning and query processing
- Data coding (acc. to MedDRA)
- Clinical data output (CDISC ODM compliance)
- Power analysis and sample size evaluations
- Biostatistical evaluations
- Statistical report writing

Some of OCT clients

- Adherex
- Bayer
- Berlin Chemie
- Boehringer Ingelheim
- Egis
- Ferring Pharmaceuticals International
- Geropharm
- GSK
- Hospira UK Limited
- Incuron
- KRKA
- Menarini International
- MYR GmbH/Hepatera
- Novartis
- Oasmia Pharmaceutical AB
- Oncopeptides AB
- Onyx Pharmaceuticals, Inc
- Pfizer European Service Center
- Pharma Bio
- Pharmsynthez
- Reckitt Benckiser
- R-Pharm
- Senju
- Sinclair Pharmaceuticals
- SynBio

Overall Indexed Clinical Trial Costs

Source: A.T. Kearny analysis

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Thank you for your attention